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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,433	02/27/2004	Mark Thomas Muldoon	19596-0571 (45738-296417)	5696
23370 7590 01/24/2007 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary

Application No.

10/789,433

Applicant(s)

MULDOON ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/2/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the reply filed on September 25, 2006 is acknowledged. The traversal is on the ground(s) that Applicants respectfully submit amino acid sequences SEQ ID NO: 2-6, 9-13 and 15-35 share physical and functional characteristics and that the sequences listed in the Markush Group are related because they are amino acid sequences. This is not found persuasive because the amino acid sequences constitute patentably distinct inventions which are distinct physically, structurally, and functionally and are therefore patentably distinct, each group from the other, and one sequence is not required to practice the other. Each sequence comprises separate and distinct amino acid sequences that do not share a substantial structural feature disclosed as being essential to the utility of the invention. Furthermore, the assertion that each amino acid elicits an immune response is not persuasive since, the amino acid sequences are patentably distinct inventions because of their distinct physical and structural identity. Furthermore, the immune response created in response to each sequence results in different antibodies being produced, therefore each sequence produces a different outcome.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing which inventions are obvious variants of each other or clearly admit on the record which inventions are obvious variants of each other. If the inventions are deemed obvious variants of each other, then if the examiner finds one of the inventions

Art Unit: 1645

unpatentable over the prior art, the evidence submitted by applicant or admission of record by applicant may be used in a rejection under 35 U.S.C. §103(a) of the other inventions.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claim Status

2. Claims 1-9 and 19 have been withdrawn from consideration. Claims 10-18 and SEQ ID NO:2 are under consideration in this office action.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

Art Unit: 1645

was filed, had possession of the claimed invention. This is a written description rejection.

Claim 17 is drawn to an assay for detecting a mammalian troponin, wherein the ligand is specific for an equine troponin I, a porcine troponin I, a bovine troponin I, or a combination thereof.

The written description in this case only sets forth specific troponins from, for example, equine, porcine, bovine species; the written description is not commensurate in scope with the claims drawn to combinations thereof. Neither the specification nor the claims teach how to define the combinations thereof. Neither the claims nor the specification teach how to obtain such combinations. There is no guidance as to what the combinations are; or what combinations can or cannot be used in the assay method being claimed. The specification does not include structural examples of combinations thereof. Thus, the resulting combination thereof could result in a complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named ligands, the skilled artisan cannot envision the detailed structure of the combination thereof, thus conception is not

achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of by only their functional activity, does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

Therefore only the recited specific ligands and not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (Clin. Biochem. 1996. Vol. 29(4): 301-308).

The claims are drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a) reacting the sample with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the

Art Unit: 1645

troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the sample. The dependant claims are to using slow or fast twitch troponin I and an antibody ligand.

Takahashi et al., teach the use of enzyme immunoassay for measurement of skeletal troponin I (TnI) utilizing isoform-specific monoclonal antibodies. Three isoforms of TnI have been identified, slow-twitch skeletal troponin I (ssTnI), fast-twitch skeletal troponin I (fsTnI) and a cardiac isoform (page 301, col.2). These isoforms have sufficient structural heterogeneity to permit the development of isoform specific antibodies (page 301, col.2). The authors not only developed a panel of monoclonal antibodies to human skeletal TnI, but also a sensitive enzyme immunoassay (ELISA) for the quantification of fsTnI in human serum samples (page 301, col.2). Therefore, the art teaches that the ligand is an antibody and the troponin molecule is a mammalian fast twitch skeletal polypeptide, just as required by the claims. Takahashi et al., used a human fsTnI to immunize a mouse and create hybridoma and anti-fsTnI antibodies (page 302, col.1). Thus the authors teach that an antibody was produced by immunizing an animal. Takahashi et al., teach the specificity of the monoclonal antibodies and using fsTnI specific antibodies as the capture antibody (page 302, col.2). The art teaches using specific monoclonal antibodies therefore the monoclonal would be specific for the mammalian troponin and not for an avian troponin, just as required by the claims. The ELISA allowed a complex to form between TnI in the sample and the labeled antibody to thereby allow detection (page 303, col. 1). Therefore the art teaches reacting the sample with an antibody ligand that is specific for mammalian fsTnI and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin; and b) detecting the complex as a measure of the presence or amount of the troponin in the sample, just as required by the claims.

Thus, Takahashi et al., teach an assay for detecting mammalian troponin I just as required by the instant claims.

6. Claims 10, 11, 13, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al., (Meat Science. 2002. Vol. 61:55-60, available on online December 21, 2001).

The claims are drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a) reacting the sample with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the sample. The dependant claims are to detecting the mammalian troponin I polypeptide, an antibody ligand specific for porcine troponin I, and the sample being from animal feed.

Chen et al., teach immunological methods for testing species authenticity of meats and meat products using porcine troponin I as a thermostable species marker protein. The art teaches that teach the several porcine specific monoclonal antibodies have been raised (page 55, col.1). Chen et al., teach the recognition and use of monoclonal antibodies as specific for skeletal troponin I (sTnI) and demonstrated the heterogeneity of sTnI which can be differentiated immunologically at the species level (page 56, col.1). Skeletal and cardiac troponin I was purified from porcine, bovine and chicken (page 56, col.1). Chen et al., also teach obtaining monoclonal antibodies from mice (page 56, col.2). Thus the art teaches using an antibody ligand and the troponin I which is a polypeptide, just as required by the claims. The samples were raw and cooked porcine muscle extracts (page 56, col. 1-2). It is noted that the specification at

Art Unit: 1645

page 5, lines 6-11 teach that the term "animal feed" refers to any substance provided to an animal for nourishment, including preparations from meat products from animals for human consumption. Therefore the use of raw and cooked porcine muscle samples, meets the limitation drawn to animal feed sample, just as required by the claims.

Immunoblotting was performed using the isolated proteins and the antigenic components were detected by the monoclonal antibody (page 56, col.2). Furthermore the art teaches an indirect ELISA using the monoclonal antibody as the detection reagent for detecting porcine sTnI (page 57, col.1). Figure 2 shows the result of detecting porcine sTnI in a sample. Therefore, Chen et al., teach reacting the sample with an antibody ligand that is specific for skeletal mammalian troponin I molecule for a time and under conditions sufficient to form a complex between the ligand and the troponin; and indirectly detecting the complex as a measure of the presence or amount of the troponin molecule in the sample. Chen et al., also teach the specificity of the monoclonal antibody 5H9 which recognized porcine sTnI but not other skeletal or cardiac troponin, or sTnI from bovine or chicken (page 58, col.2). Therefore, the art clearly teach a monoclonal antibody ligand specific for a mammalian troponin and not specific for an avian troponin, just as required by the claims.

Thus, Chen et al., teach an assay for detecting mammalian troponin I just as required by the instant claims.

7. Claims 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheng et al (J. of Bio. Chem. 1992. Vol. 367(35): 25,407-25,413).

The claims are drawn to an assay for detecting a mammalian troponin molecule in a sample, the assay comprising: a) reacting the sample with a ligand that is specific for the mammalian troponin molecule and not specific for an avian troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the

troponin molecule; and b) detecting the complex either directly or indirectly as a measure of the presence or amount of the troponin molecule in the sample. The dependant claims are drawn to the antibody being produced by immunizing an animal with a peptide having SEQ ID NO:2; the ligand binds to a peptide having SEQ ID NO:2; or the ligand binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2.

Sheng et al., teach the isolation, expression and mutation of a rabbit skeletal muscle cDNA clone for troponin I. The art teaches the cDNA clone for the mRNA that encodes rabbit fast twitch skeletal muscle TnI (page 25, 408, col.1). Sheng et al., teach the isolation and sequencing of TnI, along with its expression and purification (page 25,408, col.2). Sheng et al., teach the cDNA and the deduced amino acid sequence of rabbit fast skeletal muscle TnI in Figure 1 and the nucleotide sequence homology of rabbit, mouse and chicken TnI in Figure 2. To assess the expression, the lysate from the culture containing expressed TnI protein was transferred to nitrocellulose paper and probed with a rabbit fast skeletal muscle TnI monoclonal antibody (see the legend to Fig. 3). Therefore, Sheng et al., teach a rabbit fast skeletal muscle TnI monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 and not specific for an avian troponin, just as required by the claims. Furthermore the art teaches the production of the rabbit fast skeletal muscle TnI monoclonal antibody which inherently includes the teaching of the monoclonal antibody produced by immunizing an animal with the peptide having SEQ ID NO:2, just as required by the claims. Sheng et al., also teach a ligand that binds to SEQ ID NO:2; and a ligand that binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2, just as required by the claims.

Art Unit: 1645

Figure 3 shows that immunoblot result and detection of TnI with a monoclonal antibody. Here the art teaches reacting the culture sample with a rabbit fast skeletal monoclonal antibody ligand specific for troponin I having SEQ ID NO:2 for a time and under conditions sufficient to form a complex between the antibody and troponin I; and detecting the complex as a measure of the presence of the troponin I in the sample, just as required by the claims. Furthermore, Sheng et al., teach affinity chromatography techniques wherein troponin C and F-actin were immobilized to thereby allow the retention of the TnI or its mutant version on the affinity column, followed by elution, detection by UV adsorption and identification by SDS-PAGE and western blotting techniques (page 25,408, col.2). The art teaches detecting rabbit troponin I by reacting the sample containing the troponin I with a ligand, either troponin C or F-actin, both of which are specific for troponin I having SEQ ID NO:2 for a time and under conditions sufficient to form a complex between the ligand and troponin I; and detecting the presence of the complex by UV absorption as a measure troponin I in the sample, just as required by the claims. Sheng et al., teach ligands such as troponin C and F-actin that specifically to troponin I having SEQ ID NO:2, and those ligands will also binds to a nucleic acid molecule encoding a peptide having the amino acid sequence of SEQ ID NO:2, just as required by the claims.

Thus, Sheng et al., teach an assay for detecting mammalian troponin I just as required by the instant claims.

Prior Art

8. Hsieh et al., teach monoclonal antibodies against heat-treated troponin I muscle proteins for species identification using ELISA assays. Kluwe et al., teach SEQ ID NO:2 along with the expression and characterization of a mutant troponin I. O'Brien et al., teach differential reactivity of cardiac and skeletal muscle from various species in a

Art Unit: 1645

cardiac troponin I immunoassay. Zanellato et al., teach troponin I as expressed in bovine vascular smooth muscle and three monoclonal antibodies.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
December 8, 2006

